STEM CELL LABORATORY (STCL)

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Sysmex XS-1000i Automated Hematology Analyzer Quality Control Management

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STCL-EQUIP-002 JA1
SYSMEX XS-1000*i* AUTOMATED HEMATOLOGY ANALYZER QUALITY CONTROL MANAGEMENT

1 PURPOSE

1.1 To provide users with basic instruction regarding managing quality control lot data, qualifying new control lots, establishing ranges and executing change lot of the Sysmex® XS-1000*i* Automated Hematology Analyzer.

1.2 To provide instructions for submitting data to *Insight*™.

1.3 To discuss the purpose of Inter-Lab Quality Control

1.4 To provide instructions for establishing historical limit percents.

2 INTRODUCTION

2.1 Quality control (QC) is performed in order to monitor an instrument's performance over time. It ensures the reliability of the instrument and reagents. QC is used for long-term monitoring of the stability of analysis values. It can also detect problems early, or prevent them entirely. e-CHECK is the QC material recommended by Sysmex to monitor the performance of XS-1000*i* analyzer. It is recommended by the manufacturer to run a minimum of 2 levels of control.

2.2 The Stem Cell Lab runs controls for each shift, approximately every 8 hours. However, QC may not be required/performed on second shift if there are no patient samples that will be run after the initial 8 hour time frame expires. Control runs can also be used for troubleshooting purposes and additional control runs may be completed as necessary.

2.3 Sysmex recommends that laboratories establish their own QC Target Values for each new lot number. When the laboratory receives a new control lot, it is analyzed a minimum of 10 times, preferably twice a day for a minimum of 5 days before auto setting target values (setting mean value). Once the auto target values are set, the user can evaluate the controls by viewing e-CHECK Levy-Jennings Charts under the QC Files tab.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure is referenced when entering new control lot data and executing change lot of the Sysmex® XS-1000*i* Automated Hematology Analyzer and when submitting data to *Insight*™.

3.2 The Medical Directors, Laboratory Manager, Quality Manager, and applicable laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

4.1 QC Quality Control

4.2 L-J Levy Jennings

4.3 GP Graph Printout

4.4 LP Ledger Printout

4.5 STCL Stem Cell Laboratory

4.6 Insight™ Inter-Laboratory Quality Assessment Program

5 MATERIALS

5.1 Supplies

5.1.1 NA

5.2 Reagents

5.2.1 Four Sysmex reagents are used on the Sysmex XS-1000*i*.

5.2.2 All reagents are used at room temperature and are to be used (unopened) within the manufacturer's expiration date on each container.

5.2.3 All reagents are azide free and they are intended for *in vitro* diagnostic use only. **Do not ingest.**

REAGENT	ABBREVIATION	OPEN EXPIRATION
CELLPACK	EPK	60 days
STROMATOLYSER-4DL	FFD	60 days
STROMATOLYSER-4DS	FFS	60 days
SULFOLYSER	SLS	60 days

5.3 **e-CHECK®** (Levels 1-3) manufactured by Streck is a whole blood commercial control for use with the Sysmex® XS-1000*i* hematology analyzer.

6 EQUIPMENT

6.1 Sysmex® XS-1000*i* Hematology Analyzer

6.2 Information Processing Unit (IPU)

6.3 Graphic Printer

7 SAFETY

7.1 Use all appropriate personal protective equipment when handling laboratory controls to include, but not limited to, gloves, lab coats, goggles, etc.

8 PROCEDURE

8.1 Entering New Control Lot Data

8.1.1 Log in using the "key operator's" log on.

8.1.1.1 On the IPU screen click on File, Log Off.

8.1.1.2 Log on using the username **sysmex** and the password **c9.0**

8.1.2 Obtain the XS assay sheet from the package containing the new lot of control material.

8.1.3 Select **QC Files** and choose 3 QC files (select the 3 files with the oldest expiration dates) to use for the new lot.

8.1.4 Print out the L-J charts and the data for each of these files in preparation of clearing these files.

8.1.4.1 Click on **QC Files (F5)** in the tool bar.

8.1.4.2 Double click the desired file.

8.1.4.3 Press **CTRL [A]** to select all the data points.

8.1.4.4 Click on **Report (P)** at the top of the screen.

8.1.4.5 Select **Report (GP)(R)** to print the graphs and **Ledger(LP)(L)** to print the numerical data.

8.1.4.6 File these printouts behind the set-up sheets for the QC lot in the Sysmex QC notebook.

8.1.5 Erase these files. In order to keep the limit percents intact, clear the files by deleting only the data points.

8.1.5.1 Click on **QC Files (F5)** in the tool bar.

8.1.5.2 Double click the desired file.

8.1.5.3 Press **Ctrl [A]** to select all the data points.

8.1.5.4 Click on the **Delete** icon.

8.1.6 Set up the new QC files in these 3 cleared files.

8.1.6.1 Click on **QC Files (F5)** in the tool bar.

8.1.6.2 Double click the desired file.

8.1.6.3 Click on **Input (F9)** in the tool bar.

8.1.6.4 Click on the ▼next to **Material** and choose the level of QC.

8.1.6.5 Press the [TAB] key and enter the lot number in the **Lot No QC** box.

8.1.6.6 Click on the ▼ next to **Exp Day** and enter the expiration date.

8.1.6.7 Click on the RBC parameter, then press **[Ctrl] [Shift] [End]** simultaneously to highlight all parameters.

8.1.6.8 Click on **[VARIABLE TARGET]** to clear the target column. This will be used to establish the running mean for the control.

8.1.6.9 Click **OK**.

8.1.6.10 Repeat steps 8.1.6.1 through 8.1.6.9 for the other two levels of control.

8.2 Qualifying New Quality Control Lot and Establishing Ranges

8.2.1 Follow instructions for use and analyze each control once.

8.2.1.1 Remove vials from refrigeration and packaging. Allow at least 15 minutes to warm vials to room temperature.

8.2.1.2 Verify cap is secure and mix each vial by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.

8.2.2 Compare the results to the published assay sheet for the XS. All the values have to be within the given range for each value in each level (1-3). If out of range, repeat controls again.

8.2.3 Indicate on each QC Report for levels 1-3 "OK" if results are within acceptable range, initial and date.

8.2.4 Place reports in the designated Sysmex Quality Control binder.

8.2.5 Analyze the new QC lot, in parallel with the current QC lot, a minimum of 10 times over 5 days.

8.2.6 Once parallel testing is completed, the values are established for the new QC lot.

8.3 Auto Setting Target Values (setting mean value) and Implementing QC

8.3.1 Click **QC File (F5)** in the toolbar.

8.3.2 Double click the desired file.

8.3.3 Evaluate the data and delete any points that look aberrant by clicking on the point, clicking on **Record** and **Delete**. You do not want a spurious result to impact your target values.

8.3.4 Select all remaining data points by pressing **Ctrl [A]**.

8.3.5 Click on the **Input (F9)** icon in the toolbar.

8.3.6 Click on the RBC parameter, then press **[Ctrl] [Shift] [End]** simultaneously to highlight all parameters.

8.3.7 Click on the **Auto Setting** box.

8.3.8 Make sure the **Target** box is checked and that the **Limit** box is not checked.

8.3.9 Click **OK**.

8.3.10 Click **OK**.

8.3.11 Repeat steps 8.3.1 through 8.3.10 for the other two levels of control.

8.3.12 Auto setting target values can also be performed for readjusting ranges if having trouble with QC, for example after a calibration.

8.4 Monitoring QC

8.4.1 For daily monitoring of QC, reference STCL-EQUIP-002 FRM 1 Sysmex XS-1000i QC Review Log – DAILY.

8.4.2 For weekly/monthly monitoring of QC, reference STCL-EQUIP-002 FRM 3 Sysmex XS-1000i QC Review Log – Weekly/Monthly.

8.4.3 Submitting Sysmex/Insight™

8.4.3.1 The Insight program provides an important component of quality assessment by allowing the laboratory to assess the analyzer's average inaccuracy and imprecision relative to the peer group.

8.4.3.2 Each lot of QC is submitted to Insight twice.

8.4.3.3 Follow Sysmex calendar for submission of data during Period 1 and Period 2. The calendar can be printed from the Insight portion of the Sysmex website.

8.4.3.4 Data for Insight submission must be saved to a CD. Two CDs have been established for this purpose, one CD for use during Period 1 and a second CD for use during Period 2.

8.4.3.5 Log in using the "key operator's" log on.

8.4.3.5.1 On the IPU screen click on **File, Log Off.**

8.4.3.5.2 Log on using the username **sysmex** and the password **c9.0**

8.4.3.6 Click on **QC Files (F5)** on the toolbar.

8.4.3.7 Click the file you want to save. It will be highlighted.

8.4.3.8 Place a CD in the CD drive.

8.4.3.9 Click on the **Insight (F12)** icon.

8.4.3.10 Choose the appropriate location in the **SAVE IN** drop down box.

8.4.3.11 Verify the correct lot number and level is displayed in the "File Name" box.

8.4.3.12 Click **SAVE.**

8.4.3.13 Repeat steps 8.4.3.5 through 8.4.3.11 for the other 2 levels of control.

8.4.3.14 When the data has finished burning to the CD, remove the CD.

8.4.3.15 Log off.

8.4.3.16 Insert CD into your computer.

8.4.3.17 Go to www.sysmex.com.

8.4.3.18 Log in: User name (e-mail address) and customer password. Press [Enter].

8.4.3.19 In the Sysmex Log-in Welcome screen, select ***Insight™/Login.***

8.4.3.20 Under QC Data, select Submit QC Data.

8.4.3.21 In the Submit QC Data files screen, select analyzer **XS-1000i - 62814.**

8.4.3.22 Select Browse to find the files to submit.

8.4.3.23 Select **[File]** from Removable Disk Drive with current lot number # and ending with 801 **Select OPEN.** Then click **[Submit Data File]** and repeat for other levels ending with 802 and 803.

8.4.3.24 Click **[View QC Data Report for Open Mode For XS-1000i-62814]** to view submitted data. Lot-to-Date report is displayed.

8.4.3.25 Print and forward to lab manager for review and signature.

8.4.3.26 File report in Sysmex XS-1000i INSIGHT QC REPORTS binder.

8.4.3.27 Click **[Close]**. Click **[Log off]**. Once you log off, the data is submitted.

8.4.3.28 Remove CD.

8.5 Inter-lab Quality Control – ILQC

8.5.1 Duke University Medical Center's Department of Clinical Laboratories distributes inter-laboratory quality control samples to ensure that all laboratories are reporting statistically similar results. The program also serves as an additional check on the calibration and operation of each analyzer.

8.5.2 ILQC is distributed twice each month to nine participating laboratories. Each laboratory analyzes the two specimens and enters the results into a computer program. The results are collated and statistical comparisons are made and outliers are identified. Outliers initiate an investigation to determine the cause of any unacceptable results.

8.6 Quality Control Historical LIMIT %

8.6.1 Establishing Historical LIMIT % for Commercial Controls

8.6.1.1 For each parameter of each level of control, an acceptable range around the mean must be established. This range, called the 'LIMIT %' is based on historical performance of the commercial control material when the instrument is in good working condition.

8.6.1.2 Historical LIMIT % is established using at least three different lots of Sysmex *e*-CHECK controls (over a 6 month period for the 84-day dated lot). Interim Limit % suggested by Sysmex is used prior to establishing the analyzer-specific limits during the evaluation period. Once three lots of QC data are collected, the CV% for each parameter is averaged.

To establish a 3CV% limit, multiply the average CV's x 3. These historical limits are manually entered for the LIMIT % in each file for each level of control and are used for all subsequent lots of controls. These limits should provide acceptable error detection with a low probability of false rejection, and need not be re-established.

8.6.2 Entering QC Limit %

8.6.2.1 On the IPU, click **[QC Files]** or press **[F5]**.

8.6.2.2 Click on the appropriate file (1-20).

8.6.2.3 Click **[Input]** or press **[F9]**.

8.6.2.4 Each parameter for the level selected will be displayed in the "Manual Setting" window on the right of the "Input Lot Information" screen.

8.6.2.5 Manually enter the LIMIT % for the first parameter in the "Limit Range %" field and press **[ENTER]** on the keyboard 2 times to move to the limit for the next parameter. Repeat for all parameters of the QC level.

8.6.2.6 Click **[OK]** to save and return to QC file list.

8.6.2.7 Repeat steps 8.6.2.1-8.6.2.6 for other levels.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-EQUIP-002 Sysmex XS-1000*i* Hematology Analyzer Automated Blood Count Procedure For The STCL

9.2 STCL-EQUIP-002 FRM 1 Sysmex XS-1000*i* QC Review Log – DAILY

9.3 STCL-EQUIP-002 FRM 3 Sysmex XS-1000i QC Review Log – Weekly/Monthly

10 REFERENCES

10.1 Sysmex XS-1000*i*™ Instructions For Use

10.2 *e*-CHECK™ Hematology Control For Sysmex® X-Series Analyzers

10.3 Insight™ Website Upload and Data Entry Instructions

10.4 Insight™ Managing Your QC Data Instructions

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	B Waters-Pick	New Document – Created job aid after removing appendices from the parent procedure.

Signature Manifest

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